510(k) Summary

K032385

OCT 3 0 2003

Date
July 31, 2003

Submitter
Global Medical Co.
Box 515
4848 Highland Dr.
Salt Lake city, UT 84117

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Press-fit hip

Classification name
Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (per 21 CFR section 888.3358)

Equivalent Device
The Global Press-fit Hip is equivalent in design, materials and indications as the Foundation Hip (K991226, Encore Medical) and Progressive Hip (Biomet).

Device Description
The Global Press-fit stem is manufactured from Ti-6Al-4V alloy that conforms to ASTM F136. It is available is sizes ranging from 9mm to 17mm. The body tapers proximal to distal in the lateral and frontal planes, and lateral to medial in the sagittal plane resulting in a tri-planar wedge geometry that is conducive to axial and rotational stability. The distal stem is conical in shape with sharp splines to enhance rotational stability. Stems larger than 11mm have a coronal slot in the distal third to aid in the reduction of thigh pain.

A Morse type taper is used to attach modular femoral heads. The stem is available with neutral, and right and left anteverted necks. No calcar collar is present on this stem. The proximal lateral shoulder of the stem has a threaded hole for insertion and extraction tools.

The proximal body of the stem has a circumferential porous coating of sintered CP titanium beads (ASTM F67).

The femoral heads utilized with the Global Press-fit Hip are machined from wrought CoCrMo alloy (ASTM F799). They are available in 22mm, 28mm and 32mm diameters. The 22mm heads have two neck lengths, while the 28mm and 32mm heads have five neck lengths.

Intended Use
The Global Press-fit Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because of: degenerative joint disease, including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. It is intended for cementless use.

Summary of Technological Characteristics Compared to Predicate Device
The stem geometry of the Global Press-fit stem is similar to the Foundation Hip. They both are fabricated from Ti-6Al-4V alloy and undergo the **exact same** porous coating process. Therefore, as long as there are no geometrical features in the area where the stems would fail while being tested per ISO 7206-4 an engineering analysis is a valid method to compare the strength of these two press-fit stems.

The results of this analysis show that the strength of the Global 9mm Hip is virtually the same as the Foundation 8mm Porous Hip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

Global Medical Co.
C/o Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K032385
Trade/Device Name: Global Press-fit Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: July 31, 2003
Received: August 4, 2003

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K032385

Device Name: Global Press-fit Stem

Indications for Use:

Global Press-fit Stem
Indications for Use

The Global Press-fit Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because of: degenerative joint disease, including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. It is intended for cementless use.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____(Division Sign-off)
Division of General, Neurological and Restorative Devices

510(k) Number_____

Prescription Use ____
(per 21 CFR 801.109) OR Over-the-Counter Use ____

(Optional format 1-2-96) _____

for Mark N Milhauser
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032385